

Prescribing Information

Triumeq[▼] dolutegravir 50mg/abacavir 600mg/lamivudine 300mg tablets

See Summary of Product Characteristics (SmPC) before prescribing.

Indication: HIV in over 12 years and ≥ 40 kg. Screen for HLA-B*5701 prior to use. Do not use if HLA-B*5701 positive. **Dose:** one tablet once daily with or without food. *Elderly:* Limited data in 65+ yrs. *Creatinine clearance <50ml/min or moderate/severe hepatic impairment:* Not recommended. Monitor closely in mild hepatic impairment.

Contraindications: Hypersensitivity to any ingredient. Co-administration with dofetilide.

Warnings/precautions: Both abacavir and dolutegravir are associated with risk of hypersensitivity reactions (HSR). Do not initiate in HLA-B*5701+ or previous suspected abacavir HSR. Stop Triumeq without delay if HSR suspected. Never reintroduce any dolutegravir- or abacavir-containing product after suspected HSR. Risks of immune reactivation syndrome, osteonecrosis, increased weight, lipids, glucose. Monitor LFTs in Hepatitis B/C co-infection. Inconclusive data on relationship between abacavir and MI; minimise all modifiable CV risk factors (e.g. smoking, hypertension, hyperlipidaemia). Not recommended if dolutegravir required b.d. (with etravirine [without boosted PI], efavirenz, nevirapine, rifampicin, boosted tipranavir,

carbamazepine, oxcarbazepine, phenytoin, phenobarbital and St John's Wort). Use with cladribine not recommended. Use with Mg/Al-containing antacids, calcium, multivitamins or iron requires dosage separation. Caution with metformin: monitor renal function and consider metformin dose adjustment. When possible, avoid chronic co-administration of sorbitol or other osmotic acting alcohols (see SmPC section 4.5). If unavoidable, consider more frequent viral load monitoring.

Pregnancy/lactation: Not recommended.

Avoid breast-feeding. **Side effects:** See SmPC for details. Headache, insomnia, sleep/dream disorders, GI disturbance, fatigue, hypersensitivity, anorexia, depression, anxiety, dizziness, somnolence, lethargy, malaise, cough, nasal symptoms, rash, pruritus, alopecia, arthralgia, myalgia, asthenia, fever, elevations of ALT, AST and CPK, blood dyscrasias, suicidal ideation or suicide attempt, rhabdomyolysis, acute hepatic failure, lactic acidosis, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis.

Basic NHS costs: 30 tablets: £798.16
EU/1/14/940/001. MA holder: ViiV Healthcare UK Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS. Further information is available from Customer Contact Centre, GlaxoSmithKline UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

POM S1A

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Date of approval: July 2018

Zinc code: UK/TRIM/0037/14(11)

Adverse events should be reported. For the UK, reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for **MHRA Yellowcard** in the **Google Play or Apple App store**. Adverse events should also be reported to GlaxoSmithKline on 0800 221441.

Adverse events should be reported. For Ireland, adverse events should be reported directly to the HPRAs; Freepost, Pharmacovigilance Section, Health Products Regulatory Authority, Earlsfort Terrace, Dublin 2, Tel: +353 1 676 4971, medsafety@hpra.ie. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.

Prescribing Information

Tivicay[▼] dolutegravir 10mg, 25mg and 50mg tablets

See Summary of Product Characteristics before prescribing

Indication: HIV in >6 years and ≥ 15 kg as part of combination therapy. **Dosing:** *Adults & adolescents ≥ 40 kg:* 50mg once daily with or without food if no proven/ suspected integrase resistance. Children 6 to <12 years: dose according to bodyweight: 15-<20kg: 20mg once daily (2x10mg); 20-<30kg: 25mg once daily; 30-<40kg: 35mg once daily (1 x 25mg + 1 x 10mg); When co-administered with efavirenz, nevirapine, tipranavir/ritonavir, etravirine (without boosted PI), carbamazepine, oxcarbazepine, phenytoin, phenobarbital, St John's Wort or rifampicin, Tivicay 50mg twice daily in adults/adolescents or the weight-based once daily dose twice daily in paediatric patients. *Adults with proven/ suspected integrase resistance:* 50mg twice daily preferably with food. Limited data in paediatric patients with proven/suspected integrase resistance. *Elderly:* Limited data in 65+ yrs. Caution in severe hepatic impairment.

Contraindications: Hypersensitivity to any ingredient. Co-administration with dofetilide.

Warnings/precautions: Risk of hypersensitivity reactions. Discontinue

dolutegravir and other suspect agents immediately if suspected. Risks of osteonecrosis, immune reactivation syndrome. Monitor LFTs in Hepatitis B/C co-infection and ensure effective Hepatitis B therapy. Caution with metformin: monitor renal function and consider metformin dose adjustment. Use with etravirine requires boosted PI or increased dose of dolutegravir. Use with Mg/Al-containing antacids, calcium, multivitamins or iron requires dosage separation. **Pregnancy/lactation:** Not recommended. Avoid breast-feeding. **Side effects:** See SmPC for full details. Headache, GI disturbance, insomnia, abnormal dreams, depression, anxiety, dizziness, rash, pruritus, fatigue, elevations of ALT, AST and CPK, arthralgia, myalgia, hypersensitivity, suicidal ideation or suicide attempt, acute hepatic failure. **Basic NHS costs:** £498.75 for 30 x 50mg tablets (EU/1/13/892/001). £99.75 for 30 x 10mg tablets (EU/1/13/892/003). £249.38 for 30 x 25mg tablets (EU/1/13/892/005). MA holder: ViiV Healthcare BV, Huis ter Heideweg 62, 3705 LZ Zeist, Netherlands. Further information available from Customer Contact Centre, GlaxoSmithKline UK Ltd, Stockley Park West, Uxbridge, Middlesex UB11 1BT.

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Zinc code: UK/DLG/0055/13(14)

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